REMARKS

1. STATUS OF THE CLAIMS

Claims 1-21 are pending in the present application.

Claims 19-20 have been cancelled in response to a restriction requirement without prejudice to their renewal in a future application. This does not narrow the scope of any of the claims within the meaning of *Festo*,[1] because cancellation of non-elected claims in not related to a "statutory requirements for a patent" but rather is related to the Patent Office's convenience for organizing searches. Applicant reserves the right to prosecute the cancelled (or similar) claims in another application(s).

Claims 1 and 2 have been amended to recite a nucleic acid sequence "encoding factor IX protein" in view of Applicant's election of this species of nucleic acid sequence.

Claims 1 and 2 have also been amended to recite that the promoter is a "human Factor IX" promoter to reflect Applicant's election of this species of promoter.

Claims 1 and 2 have been amended to recite an age regulatory sequence "consisting of one or more of SEQ ID NO:3, SEQ ID NO:91, and SEQ ID NO:93 wherein said age regulatory sequence is located 3' of said nucleic acid sequence encoding Factor IX protein" to reflect Applicant's election of the age regulatory sequences SEQ ID NOs:3, 91, and 93.

The preamble of Claim 2 has been amended for uniformity with the language in step c) of the claim.

Claim 3 has been amended to recite a nucleic acid sequence "consisting of" SEQ ID NO:93 to illustrate one embodiment of the invention.

Claims 4, 7-11, 14, and 16-20 have been cancelled to avoid redundancy with pending claims as amended.

Claim 5 has been amended, and new Claim 22 has been added, to recite that the "age regulatory sequence consists of SEQ ID NO:93." Support is in the Specification on, for example,

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, U.S., No. 00-1543, 5/28/02.

page 36, lines 3-10 which say that "The invention further provides the nucleotide sequence AE3" which is a preferred portion of AE3'. AE3" [5'-ttgggg gaaaagtttc tttcagagag ttaagttatt ttatatatat aatatatata taaaatatat aatatacaat ataaatatat agtgtgtgtg tgtatgcgtg tgtgtagaca cacacgcata cacacatata atggaagcaa taagccat-3'; (SEQ ID NO:93)] is the 154-nucleotide nucleic acid sequence from 35,075 to 35,228 of GenBank accession number K02402, which corresponds to the sequence from 32,110 to 32,263 of Figure 8 when in relation to the hFIX start codon (ATG) in which the adenine is designated as position +30. AE3" contains a 102-bp stem-loop forming sequence (SEQ ID NO:91)."

Claim 6 has been amended to recite a nucleic acid sequence "consisting of SEQ ID NO:91" as supported by the above exemplary disclosure in the Specification.

Claim 12 has been amended, and new Claims 23-25 and 27-29 have been added, to recite including an additional "age regulatory sequence consisting of SEQ ID NO:1" in the expression vector in combination with SEQ ID NO:3 and/or one or more of its portions SEQ ID NO:91, and SEQ ID NO:93. This combination is supported in the Specification, paragraph bridging pages 30-31, which refers to the surprising synergy in age-related regulatory activity of the combination of SEQ ID NO:1 (AE5') and SEQ ID NO:3 (AE3') and portions thereof as follows: "Importantly, the invention demonstrates the surprising synergistic action of AE5' and AE3' which together result in hFIX mRNA levels which not only are greater at each time point tested over the life span of transgenic animals (Figures 4 B and D) as compared to hFIX mRNA levels in transgenic animals harboring vectors that lack both AE5' and AE3', but also that the profile of increased human FIX mRNA levels over the life span of transgenic mouse recapitulates the profile of increased mouse FIX mRNA levels as a wild-type mouse ages." The Specification, page 31, lines 7-8, also says that "The present invention is not limited to SEQ ID NOs:1 and 3 but specifically contemplates portions thereof."

Claims 13, 15 and 21 have been amended to recite that the cell is "mammalian" to reflect Applicant's election of this species of host cell.

Claims 13, 15 and 21 have also been amended to recite that the mammalian cell is "isolated" as exemplified by the Specification's following disclosure on page 60, lines 27-28, of the exemplary embryonic stem cells *in vitro*: "The advantages of using ES cells include their ability to form permanent cell lines *in vitro*, thus providing an unlimited source of genetic

material."

Claim 21 has been amended to change its form from a dependant to an independent claim so that the preamble "A treated cell" has antecedent basis.

New Claim 26 has been added to recite an "age regulatory nucleic acid sequence consisting of SEQ ID NO:3" as supported by the Specification at numerous places such as page 28, lines 14-18.

New Claim 30 has been added to recite that the cell is a "gamete" as supported in the Specification on page 3, lines 19-20 which says "In another preferred embodiment, the host cell is a gamete."

Claim cancellations and amendments were made to describe particular embodiments of the invention, notwithstanding Applicant's belief that the cancelled and unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicant's business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).[2]

2. ELECTION OF SPECIES

Applicant notes that the Examiner made the prior requirement for restriction of species final and that the following species were examined: SEQ ID NO:144 (the elected species), SEQ ID NO:91 (contained within SEQ ID NO:144), and SEQ ID NO:93 (a portion of SEQ ID NO:3 previously examined).[3]

3. WITHDRAWAL OF PRIOR REJECTIONS

Applicant notes, with appreciation, the withdrawal of the following prior rejections:

A. Rejection under 35 USC 112, first paragraph, for alleged lack of written description,

B. Rejection under 35 USC 102(e), for alleged anticipation by Stafford *et al.*(IS

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2 65 Fed. Reg. 54603 (September 8, 2000).

3 Office Action, page 3, second and third paragraphs.

6,531,298), and

C. Rejection under 35 USC 102(b), for alleged anticipation by Clark (WO 95/3000).

4. PRIORITY IN COMPLIANCE WITH 37 CFR 1.78(a)

The Examiner noted that this application must include its relationship to the priority application in compliance with 37 CFR 1.78(a). The Specification has been amended to state that this application is a continuation-in-part of, and has priority to United States Patent Application No. 09/328,925.

5. CLAIMS OBJECTIONS

The Examiner objected to a grammatical error in Claims 1-2 which recite the phrase "said age regulatory sequences consists of."[4] Amendments to Claims 1 and 2 moot this rejection.

6. CLAIM REJECTIONS

Claims 1-18 and 21 have been rejected on the following grounds:

A. Claims 13-16 were rejected under 35 USC 101 for allegedly encompassing non-statutory subject matter,

B. Claims 1-2, 4-5, 7-18 and 21 stand rejected under 35 USC 112, first paragraph, for alleged non-enablement,

C. Claims 4-5 stand rejected under 35 USC 112, second paragraph, for alleged indefiniteness,

D. Claims 1-13, 16-17 and 21 were rejected under 35 USC 102(b) as being anticipated by Kurachi *et al.*,

E. Claims 1-18 and 21 were rejected under 35 USC 102(b) as being anticipated by Jallat *et al*,. and

F. Claims 1-11, 13, 15-17 and 21 were provisionally rejected for alleged obviousness-type double patenting over Claims 6-8 and 10 of co-pending Application No.

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[4] Office Action, page 4, third paragraph.

11/129,861.

Applicant addresses the above rejections as follows.

A. Rejection of Claims 13-16 Under 35 USC 101 (Subject Matter)

Claims 13-16 were rejected under 35 USC 101 for allegedly encompassing non-statutory subject matter.[5] The Examiner argued that the term "host cell" encompasses a cell capable of generating a multicellular organism, including a human, which is a non-statutory subject matter. Applicant has amended independent Claim 13 to recite that the host cell is "isolated." Applicant notes that this language comports with language that was proposed by the Examiner for Claim 2.[6] Accordingly, withdrawal of this rejection is respectfully requested.

B. Rejection of Claims 1-2, 4-5, 7-18 and 21 Under 35 USC 112, First Paragraph (Enablement)

Claims 1-2, 4-5, 7-18 and 21 stand rejected under 35 USC 112, first paragraph, for alleged non-enablement.[7] Applicant first notes that rejected Claims 4, 7-11, 14, and 16-18 have been cancelled, therefore this rejection is moot with respect to these Claims.

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5 Office Action, page 4, last paragraph.

6 Office Action, page 5, last paragraph.

7 Office Action, page 5, fourth paragraph.

The Examiner recognized that the Specification is "enabling for . . . A recombinant expression vector comprising in operable combination i) a nucleic acid sequence of interest, ii) a promoter sequence and iii) one or more age regulatory sequences selected from SEQ ID NO:3 and a nucleic acid sequence comprising SEQ ID NO: 91, wherein the age regulatory sequences are located 3' of said nucleic acid sequence of interest."[8] In addition, the Examiner was of the opinion that the specification does not reasonably provide enablement for "any other portions of SEQ ID NO:3 or SEQ ID NO:93."[9] In other words, the Examiner found the Specification enabling for SEQ ID NOs:3, 91, and 93 when located at the 3' end of the sequence to be expressed. Amended Claim 1, and dependent Claims 5 and 12 recite the limitations found enabled by the Examiner with respect to SEQ ID NOs:3, 91 and 93 and their location. Therefore, Claims 1, 5 and 12 are enabled.

The Examiner also recognized that the Specification is "enabling for . . . An isolated host cell or a non-human host cell containing the same recombinant expression vector."[10] Rejected Claims 13 and 15, and newly added Claim 28, recite elements that the Examiner found were enabled, and are therefore enabled.

The Examiner further admitted that the "Specification is enabling for . . . A method of expressing a nucleic acid sequence of interest into a cell, comprising: a) providing: i) a cell, ii) a nucleic acid sequence of interest, iii) a promoter sequence, and iv) one or more age regulator sequences selected from SEQ ID NO:3 and a nucleic acid sequence comprising SEQ ID NO: 91, b) operably lining said nucleic acid sequence of interest, said promoter sequence and said one or more age regulatory sequences, wherein the age regulatory sequences are located 3' of said nucleic acid sequence of interest to produce a transgene, and c) introducing said transgene into said cell to create a treated cell under condition such that said nucleic acid sequence of interest is expressed in said treated cell."[11] Rejected Claim 2 as amended, and dependent new Claims 22

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8 (Emphasis added) Office Action, page 5, one but last paragraph.

9 Office Action, page 6, last full paragraph.

10 Office Action, page 5, last paragraph.

11 Office Action, paragraph briding pages 5-6.

and 23 recite the limitations found enabled by the Examiner (including SEQ ID Nos:3, 91 and 93 as discussed above). Therefore, Claims 2, 22 and 23 are enabled.

Applicant also notes that Claim 21 as currently amended recites isolated mammalian cells produced by the method of Claim 2 that is enabled. Since the base Claim 2 is enabled, then Claim 21 must also be enabled.

In view of the above, withdrawal of this rejection is respectfully requested.

C. Rejection of Claims 4-5 Under 35 USC 112, Second Paragraph (Indefiniteness)

Claims 4-5 stand rejected under 35 USC 112, second paragraph, for alleged indefiniteness on the ground that the preamble of Claims 4 and 5 recites "The nucleic acid sequence of Claim 1" which is different from the preamble of Claim 1 from which these claims depend.[12] Applicant has cancelled Claim 4, without prejudice, and amended Claim 5 to recite the same preamble as Claim 1 to avoid potential ambiguity. Applicant therefore requests withdrawal of this rejection.

D. Rejection of Claims 1-13, 16-17 and 21 Under 35 USC 102(b) Over Kurachi *et al.* (Anticipation)

Claims 1-13, 16-17 and 21 were rejected under 35 USC 102(b) as being anticipated by Kurachi *et al.* as evidenced by Yoshitake *et al.*[13] The Examiner argued that Kurachi *et al.* disclose expression vectors that "contain the 3' UTR having SEQ ID NO:3 that contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144."[14] The Examiner also opined that "the open language term 'comprising' allows the incorporation of flanking

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12 Office Action, page 10, last two paragraphs.

13 Office Action, page 11, fourth paragrpah.

14 (Emphasis added) Office Action page 12, first paragraph.

sequences to either SEQ ID NO:93 or SEQ ID NO:91."[15]

Applicant draws the Examiner's attention to the following amendments that clarify the difference between the rejected claims and Kurachi *et al.* First, Applicant has amended the term "nucleic acid sequence of interest encoding Factor IX protein" by deleting the term "of interest." This overcomes the Examiner's argument that "the nucleic acid sequences flanking either SEQ ID NO:93 or SEQ ID NO:91 are parts of a nucleic acid sequence of interest."

Second, the Examiner's attention is respectfully drawn to the recitation in amended independent Claims 1 and 2 of "an age regulatory sequence consisting of one or more of SEQ ID NO:3, SEQ ID NO:91, and SEQ ID NO:93." In contrast, Kurachi *et al.*'s 3'UTR contained, but did not consist of, SEQ ID NO:3, SEQ ID NO:91, and SEQ ID NO:93.

Third, Applicant has amended Claim 1 to recite that the vector "consists" of the recited components. Therefore, independent Claim 1, and Claims 5, 12, 13, 15 and 20 which depend from it are novel. Similarly, Claim 2, and Claims 21-23, and 29-30 which depend from it are also novel.

With respect to independent Claim 3 and dependent Claim 24, these claims recite "A substantially purified age regulatory nucleic acid sequence consisting of SEQ ID NO:93." This is distinguished from Kurachi *et al.* whose 3'UTR contained, but did not consist of, SEQ ID NO:93.

Regarding independent Claim 6 and dependent Claim 25, both these claims recite "A substantially purified age regulatory nucleic acid sequence consisting of SEQ ID NO:91." This is unlike Kurachi *et al.*'s 3'UTR that contained, but did not consist of, SEQ ID NO:91.

As to independent Claim 26 and dependent Claim 27, these claims recite "A substantially purified age regulatory nucleic acid sequence consisting of SEQ ID NO:3." This is not anticipated by Kurachi *et al.*'s 3'UTR that contained, but did not consist of, SEQ ID NO:3.

In view of the above, each of the claims is distinguished from Kurachi *et al.* Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 USC 102(b).

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15 *Id.*

E. Rejection of Claims 1-18 and 21 Under 35 USC 102(b) Over Jallat *et al.* (Anticipation)

Claims 1-13 and 21 were rejected under 35 USC 102(b) as being anticipated by Jallat *et al.* (WO 91/02056) as evidenced by Jallat *et al.* (US 5,814,716) and Anson *et al.*[16] The Examiner argued that "the expression vector constructs of Jallat *et al.* contain the 3' UTR having a sequence that contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144." However, each of the pending claims as currently amended is distinguished from Jallat *et al.* that does not disclose an "age regulatory nucleic acid sequence consisting of" the recited SEQ ID NO:3, SEQ ID NO:93, SEQ ID NO:91, and SEQ ID NO:1. Rather, Jallat *et al.* arguably contains the recited sequences. In view of this, withdrawal of the rejection under 35 USC 102(b) over Jallat *et al.* is respectfully requested.

If the Examiner disagrees with the above, the Examiner is respectfully invited to propose alternative language to overcome this rejection.

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16 Office Action, page 13, fourth paragraph.

F. Provisional Rejection of Claims 1-11, 13, 15-17 and 21 For Obviousness-Type Double Patenting Over Co-Pending Application No. 11/129,861

Claims 1-11, 13, 15-17 and 21 were provisionally rejected for alleged obviousness-type double patenting over Claims 6-8 and 10 of co-pending Application No. 11/129,861.[17] The Examiner argued that the specific age regulatory portions recited in the rejected claims cannot be considered to be patentably distinct over "SEQ ID NO:3 and a functional portion of SEQ ID NO:3, when the disclosed SEQ ID NO:3 contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144."[18] Applicant submits herewith a Terminal Disclaimer under 37 C.F.R. 1.321(c) over any patent that issues in U.S. Patent Application No.11/129,861. Accordingly, this rejection should be withdrawn.

The Examiner is respectfully reminded that ". . . filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection." *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991); see also MPEP 804.02.

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17 Office Action, page 15, fifth paragraph.

18 Office Action, page 16, first paragraph.

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CONCLUSION

All grounds of rejection and objection of the Office Action of August 9, 2007 having been addressed, reconsideration of the application is respectfully requested. Applicant respectfully request the Examiner to call the undersigned before drafting another written communication, if any.

Dated: October 31, 2007

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